emulsion of claim 5, the concentrate is not an emulsion. One could make the concentrate without infringing claim 5. Therefore, it is respectfully submitted that claim 5 is not duplicative of claim 1.

Claims 1-5 are rejected under 35 U.S.C. 103(a) over EP 296,122 A2 (Bollinger), in view of Windholz and Osol. Applicants respectfully traverse the rejection.

In order for the invention to be prima facie obvious, there must be some suggestion or teaching in the prior art, or some compelling scientific reason, that would motivate one skilled in the art to do, not try, what Applicants are claiming. As noted by the Examiner, Bollinger teaches that cyclosporins are used in reversing resistance to chemotherapy and that they may be administered parenterally or intravenously. Bollinger does not suggest or teach that one must use a combination of ethanol and stabilizer as claimed, let alone that the concentrate also must be free of POE-40 castor oil. In the instant case, Applicants respectfully submit that the Examiner has not met the burden of establishing a prima facie case of obviousness. Specifically, it is respectfully submitted that the Examiner has not indicated or pointed out what in the references would suggest to one skilled in the art or compel one skilled in the art to select a combination of the specific cyclosporin, ethanol and claimed stabilizer, in the claimed ranges, and then to exclude POE-40 castor oil from the concentrate. While both ethanol and oleic acid or salts thereof may be known solvents for pharmaceutical use, in general, these are two solvents of a multitude of pharmaceutically acceptable solvents and there is no suggestion that one should use them in combination for the specific cyclosporin. As there is no suggestion to use them together in the first place, there similarly is no suggestion that the stabilizer and active agent must be used within the claimed ratio. The standard for obviousness is obvious to do, not obvious to try. Claim 5 further requires the presence of a placebo fat emulsion. There is no suggestion or teaching in any of the above references with respect to emulsions, per se, or that one should use a placebo fat emulsion in combination with a POE-40 castor oil-free concentrate as claimed in claim 1.

Based on the foregoing, Applicants respectfully submit that the pending claims are patentable over Bollinger in view of Windholz and Osol and respectfully request that the rejection thereof under 35 U.S.C. 103(a) be withdrawn.

Claims 1-5 are rejected under 35 U.S.C. 103(a) over WO 95/31969 (Backlund). Applicants respectfully traverse the rejection.

The pharmaceutical composition of Backlund comprises a "microemulsion" made up of a hydrophilic component, e.g. water or a mixture of water and a pharmaceutically acceptable alcohol, a lipophilic component, e.g. hydrocarbon, fatty acid, a mono-, di, or triglyceride of a fatty acid or mixtures thereof, a surfactant, e.g. phospholipids, wherein the lipophilic and hydrophilic components are dispersed one in the other to form a colloidal emulsion. The particularly preferred lipophilic

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component is castor oil. In the examples, only castor oil and paraffin oil are used as lipophilic components and cyclosporin is never used at a ratio of 10:1- 400:1 with respect to the lipophilic component. Applicants respectfully submit that, with respect to claims 1-4, there is no suggestion or compelling scientific reason in Backlund which would motivate one skilled in the art to make a concentrate according to the present invention by first selecting the specific cyclosporin, dissolving the cyclosporin in ethanol and the selected stabilizer, as claimed, at the selected ratio of active agent:stabilizer claimed, and then to require that the concentrate be free of POE-40 castor oil. In fact, Applicants respectfully submit that Backlund would lead one away from Applicants' invention and that Applicants have proceeded contrary to the teachings of Backlund, when taken as a whole. Regarding, claim 5, as Backlund fails to teach or suggest the concentrate of claims 1-4, so does Backlund fail to teach an emulsion that comprises the concentrate and a placebo fat emulsion.

Based on the foregoing, Applicants respectfully submit that the pending claims are patentable over Backlund and respectfully request that the rejection thereof under 35 U.S.C. 103(a) be withdrawn.

If there are any additional fees due in connection with this communication, including any fees for an extension of time, such an extension is requested and the Commissioner is authorized to charge the fees to Deposit Account No. 19-0134 in the name of Novartis Corporation.

Respectfully submitted,

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